GUIDANT

REVISED DRAFT

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TITLE: IFU, NEUROLINK® STENT & DELIVERY CATHETER

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This version may not be purchased.

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GUIDANT

NEUROLINK® Stent & Delivery Catheter

HUMANITARIAN DEVICE: The Guidant NEUROLINK Stent & Delivery Catheter is authorized by Federal law for use in treatment of recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5mm to 4.5mm in diameter with >50% stenosis and that are accessible to the Stent system.

The effectiveness of this device for this use has not been demonstrated.

CAUTION: Federal Law (USA) restricts this device to sale, distribution, and use by or on the order of a physician.

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1.0 DEVICE DESCRIPTION

The NEUROLINK® System is comprised of the NEUROLINK® Stent & Delivery Catheter and the NEUROLINK® Balloon Dilatation Catheter. The Stent is made of medical grade 316L stainless steel, is pre-mounted on the balloon of the Delivery Catheter, and is balloon-expandable to specified diameters. The Stent is mounted on Delivery Catheters with corresponding balloon diameters that expand the Stent to different diameters between 2.5mm and 4.5mm, in increments of 0.5mm.

The Delivery Catheter is an over-the-wire, co-axial catheter design, with a balloon located at the distal end. It is designed to expand the Stent to specific diameters at specified pressures. The distal shaft of the Delivery Catheter has a hydrophilic coating that is activated when hydrated. Proximal and distal radiopaque markers are positioned within the balloon to demarcate the Stent edges, and are used to facilitate accurate Stent positioning within the target lesion. The side arm of the two-arm adapter at the proximal end of the Delivery Catheter provides access to the balloon inflation lumen and has a luer-lock fitting for the connection of an inflation device. The central arm of the two-arm adapter provides access to the guide wire lumen.

Table 1. *In vitro* Device Specifications

Stent Diameter (mm)	Stent Length (mm)	Minimum Guiding Catheter Compatibility[1]	Expanded Stent Length (mm)[2]	Rated Burst Pressure – RBP (atm)
2.5	8	6F / 0.062"/1.57mm	7.8	10
3.0	8	6F / 0.062"/1.57mm	7.5	10
3.5	8	6F / 0.062"/1.57mm	7.3	10
4.0	8	6F / 0.062"/1.57mm	6.7	10
4.5	8	6F / 0.062"/1.57mm	6.4	10
2.5	16	6F / 0.062"/1.57mm	16.0	10
3.0	16	6F / 0.062"/1.57mm	15.9	10
3.5	16	6F / 0.062"/1.57mm	15.9	10
4.0	16	6F / 0.062"/1.57mm	15.3	10
4.5	16	6F / 0.062"/1.57mm	14.6	10

1) Refer to the individual manufacturer specifications to confirm the guide catheter inner diameter (F) equivalent.
2) Expanded Stent length at nominal diameter. Refer to the compliance chart for accurate sizing information.

Ensure full deployment of the Stent (see Clinician Use Information Stent Deployment Procedure).

NOTE: LABELED STENT DIAMETER REFERS TO EXPANDED STENT INNER DIAMETER.

Table 2. Device Specifications for the NEUROLINK® Stent & Delivery Catheter

Product	Stent Diameter(s) (mm)	Stent Lengths (mm)	Crossing Profile (inches)	Expanded Stent Length (mm)
NEUROLINK® Stent & Delivery Catheter INFLATION PRESSURES RBP 10atm Nom. 5.5-7.0atm (8mm) Nom. 6.5-7.5atm (16mm)	2.5 3.0 3.5 4.0 4.5	8	0.044" – 0.049"	7.8 7.5 7.3 6.7 6.4
	2.5 3.0 3.5 4.0 4.5	16	0.046" – 0.051"	16.0 15.9 15.9 15.3 14.6

2.0 INTENDED USE/INDICATIONS

The NEUROLINK Stent and Delivery Catheter is used in the treatment of recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5mm to 4.5mm in diameter with ≥50% stenosis and that are accessible to the Stent system.

3.0 CONTRAINDICATIONS

The NEUROLINK Stent and Delivery Catheter is contraindicated for use in:

- Lesions that are highly calcified or otherwise could prevent access or appropriate expansion of the Stent.
- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated.

4.0 WARNINGS

- Persons allergic to 316L stainless steel may suffer an allergic reaction to this Stent implant.
- Implantation of the Stent should be performed only by physicians with interventional training and thorough knowledge of angiographic techniques.
- Experience with stent implants indicates that there is a risk of restenosis. Subsequent restenosis may require repeat dilatation of the vessel segment containing the stent. The risks and long term outcome following repeat dilatation of endothelialized stents is unknown at present.
- If the Stent is implanted adjacent to or contacting other implanted metal, such as another stent or an embolic coil, the metals should be of similar composition to avoid galvanic corrosion potential.

5.0 PRECAUTIONS

5.1 Stent & Delivery Catheter Handling – Precautions

- For single use only. Do not resterilize or reuse the device. Note product "Use By" date.
- Follow the Delivery Catheter preparation instructions carefully as described in Section 11.3 Preparation. Do not prepare or pre-inflate the Delivery Catheter prior to Stent deployment other than as directed.

- Do not remove the Stent from its Delivery Catheter. Removal may damage the Stent and/or lead to Stent embolization. The Stent and Delivery Catheter are intended to perform as a single device and must not be altered.
- Special care must be taken not to handle or in any way disrupt the Stent on the Delivery Catheter. This is most important during Delivery Catheter removal from its packaging, placement over the guide wire, and during advancement through the rotating hemostatic valve and guiding catheter hub.
- Do not "roll" the mounted Stent with your fingers, as this action may loosen the Stent from the delivery balloon.
- The Delivery Catheter should not be used in conjunction with other stents.
- Do not exceed the Rated Burst Pressure specified on the product label. Balloon pressure must be monitored during inflation. Use of pressures higher than that specified on the product label may result in a ruptured balloon with possible intimal damage, vessel dissection, and/or vessel rupture.

5.2 Stent Placement – Precautions

- Implanting a Stent may lead to dissection of the vessel distal and/or proximal to the Stent and may cause acute closure of the vessel, requiring additional intervention (further dilatation, placement of additional stents, or other treatment).
- Inadequate stent apposition to the vessel wall and/or inadequate stent expansion is believed to be correlated with risk of stent thrombosis and/or restenosis. Size the Stent to the reference vessel diameter and confirm optimal expansion. Post-dilatation with the Delivery Catheter or Balloon Dilatation Catheter can be used to optimize Stent deployment.
- Do not expand the Stent if it is not properly positioned in the vessel.
- Placement of the Stent may compromise side branch patency.
- Use only the recommended balloon inflation medium (see Section 11.2 Materials Required). Do not use air or any gaseous medium to inflate the balloon as this may cause uneven expansion in deployment of the Stent and carries a risk of air embolization.
- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the vasculature and/or the vascular access site. Complications may include bleeding, hematoma, or pseudoaneurysm.

5.3 Post-Implant - Precautions

- Care must be exercised when crossing a newly deployed Stent with a guide wire, balloon, or Delivery Catheter to avoid disrupting the Stent geometry or its position within the vessel.
- Anti-platelet and/or anticoagulant medical therapy is an important adjunct to Stent treatment. Patients must be advised to take their prescribed medications after the Stent is implanted, and should be counseled in the risk of not complying with medical therapy.
- The NEUROLINK® Stent has been shown to be safe with diagnostic magnetic resonance imaging (MRI) at field strengths up to and including 1.5 Tesla. MR imaging quality may be compromised if the area of interest is relatively close to the position of the Stent.

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6.0 ADVERSE EVENTS

6.1 Potential Adverse Events

Adverse events listed below may be associated with the use of the NEUROLINK Stent and Delivery Catheter in intracranial arteries.

- Acute myocardial infarction
- Death
- Dissection
- Drug reactions to anti-platelet or anticoagulant agents or contrast medium
- Distal emboli (air, tissue or thrombotic emboli)
- Fistula
- Hemorrhage requiring transfusion
- Hypotension/hypertension
- Infection and pain at access site
- Intracranial hemorrhage
- Ischemia, cerebral
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm, vessel
- Stent deformation
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of an intracranial artery
- Vessel perforation or rupture
- Vessel spasm

6.2 Observed Adverse Events

Sixty-one (61) patients have been enrolled in a multi-center, prospective, non-randomized, international clinical trial to evaluate the safety and feasibility of the NEUROLINK System for the treatment of symptomatic atherosclerotic lesions in extracranial vertebral and intracranial arteries. Adverse events were recorded for the procedure and for a mean follow-up of 216 days on the 61 patients. Twenty-four types of adverse events were recorded for 29 of 61 patients (47.5%). Twenty (20) patients had one adverse event, five (5) patients had two events, three (3) patients had three events, and one (1) patient had four events. Twenty (20) adverse events were related to the device and/or procedure; 18 events were not related, and the relationship is pending review in five (5) events. For one (1) event, additional information is pending.

Table 3 identifies the adverse events observed in the clinical study conducted to evaluate the safety and probable benefit of the NEUROLINK® System. Sixty-one patients were enrolled in the study and information is presented on all patients through 30 days and on 48 patients who have reached the 6 month follow-up time point (See Section 7, Clinical Experience).

Table 3 Adverse Events

Event	# (%) (N=61)	Time of Occurrence			Device / Procedure Related		
		Proced[1]	<30 days	>30 days	Yes	No	Pending[2]
Stroke	8 (13.1%)	4[3, 4]	0	4[5]	5	2[6, 7]	1
TIA	4 (6.6%)	0	1	3	3[8]	1[9]	0
Access Site Infection	1 (1.6%)	0	1	0	1	0	0
Ankle Swelling	1 (1.6%)	0	0	1	0	1	0
Arterial Dissection	2 (3.3%)	2	0	0	2	0	0
Atrial Fibrillation	1 (1.6%)	0	0	1	0	1	0
Bradycardia	1 (1.6%)	1	0	0	1	0	0
Cancer (Pancreatic)	2 (3.3%)	0	0	2	0	0	2
Carotid Cavernous Fistula	1 (1.6%)	1[10]	0	0	1	0	0
Congestive Heart Failure	2 (3.3%)	0	1[11]	1	0	2	0
Diabetes Mellitus (new)	1 (1.6%)	0	0	1	0	1	0
Dysesthesia	2 (3.3%)	0	0	2	0	2	0
Ecchymosis (eye)	1 (1.6%)	1	0	0	1	0	0
Fractured Spine	1 (1.6%)	0	0	1	0	1	0
Kidney Stones	1 (1.6%)	0	0	1	0	1	0
Nerve Paresis (6th)	1 (1.6%)	1	0	0	1	0	0
Neurologic Symptoms	2 (3.3%)	0	0	2	1[12]	0	1[13]
Peripheral Vascular Disease	1 (1.6%)	0	0	1	0	1	0
Rehospitalized for revascularization of asymptomatic stenosis	2 (3.3%)	0	0	2	2[14, 15]	0	0
Stent Occlusion (Acute)	1 (1.6%)	1[16]	0	0	1	0	0
Syncope	2 (3.3%)	0	0	2	0	1	1
Thrombocytopenia	1 (1.6%)	0	1	0	0	1	0
Vertebral Artery Bypass	1 (1.6%)	0	0	1	1	0	0
Vertigo	3 (4.9%)	0	0	3	0	3	0

(1) 'Procedural' means that the event occurred at the time of the procedure or within the same hospitalization but not in excess of 30 days within the same hospitalization

(2) Event is pending adjudication by the Clinical Events Adjudication Committee

(3) Three strokes were adjudicated as major in severity, one as minor

(4) Two of these patients later died

(5) One of these patients later died

(6) No Stent was implanted in one of these patients. Stroke occurred five months post-procedure and is adjudicated as not related to the test device or procedure

(7) Adjudicated as not related to the test device or procedure, minor and ipsilateral, due to local microvascular thrombosis

(8) One of these TIAs was previously reported as, "possible re-emergence of stroke symptoms". CEAC adjudicated event as "TIA, probably related to test device and procedure".

(9) Per investigator, symptoms occurred after six-month angiogram and are not related to the test device, but are probably related to pre-existing condition or may be reaction to contrast dye used for the six-month angiogram.

(10) Occurred at the time of the procedure, but did not require treatment until after 30 days

(11) Exacerbation of existing congestive heart failure at 20 days post-procedure

(12) Symptoms consistent with malperfusion syndrome related to restenosis of the target lesion. Stroke and TIA ruled out. Target lesion revascularization by balloon angioplasty.

(13) Symptoms of facial droop and incontinence which resolved in 15 minutes. Ruled out stroke and TIA.

(14) Six-month angiogram demonstrated 71% in-stent restenosis; neurologic exam and stroke scale scores unchanged. Patient anxious and requested treatment. Target lesion revascularization using PTA, with residual stenosis of 46%. Follow-up unremarkable.

(15) Patient asymptomatic but restenosis determined to be "hemodynamically relevant" therefore target lesion revascularization performed with PTA.

(16) Lytic (10mg rt-PA) was administered and occlusion resolved with no clinical sequelae.

7.0 CLINICAL EXPERIENCE

7.1 SSYLVIA: Stenting of SYmptomatic atherosclerotic Lesions in the Vertebral and Intracranial Arteries

The NEUROLINK® System was designed for the treatment of recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy. The SSYLVIA clinical study is a prospective, non-randomized, multi-center, international study and is ongoing. The objective of the study is to evaluate the safety and feasibility of the NEUROLINK System for the treatment of symptomatic atherosclerotic lesions in the extracranial vertebral and intracranial arteries. Patients were eligible for participation in the study if they were symptomatic (previous stroke or TIA) due to an angiographically demonstrated, discrete stenosis >50% and ≤5mm in length in an extracranial vertebral or intracranial artery between 2.5mm and 4.5mm in diameter. The clinical study evaluated stent use in a broader patient population than that characterized in the Humanitarian Use Device (HUD) designation.

All patients were required to receive an antiplatelet regimen beginning at least 48 hours prior to the procedure. This consisted of aspirin (minimum 100mg twice daily) and Clopidogrel (75mg twice daily). Heparin was administered during the Stent implantation procedure to maintain the activated clotting time (ACT) at a therapeutic level of 200 to 300 seconds.

The NEUROLINK® Balloon Dilatation Catheter could be used to predilate the lesion to facilitate access by the NEUROLINK Stent and Delivery Catheter. Both the Balloon and Stent were sized in a 1:1 ratio to the smaller of the diameters of the vessel proximal or distal to the lesion. Post-dilatation with either the Delivery Catheter or the Balloon Dilatation Catheter could be used to optimize Stent apposition and residual stenosis. Post-procedure, dual antiplatelet therapy was required. This consisted of aspirin daily for a minimum of one (1) year, plus Clopidogrel for a minimum of four (4) weeks. Device and procedural safety were determined by analyzing acute and 30-day individual endpoints, and all adverse events. All primary endpoints were analyzed on an intent-to-treat basis.

The primary endpoints for safety for this study are: Composite Death and Stroke at 30 days, Death at 30 days, and Non-Fatal stroke at 30 days. All patients are required independent neurologic examinations (performed by the non-operator stroke neurologist investigator) at one, three, six, and 12 months. Angiographic assessment of the stented lesion is required at six months. All procedure and follow-up angiograms are analyzed by an independent Angiographic Core Laboratory. Major clinical events are adjudicated by an independent Clinical Events Adjudication Committee. The Data Safety Monitoring Board (DSMB) is responsible for review of the cumulative safety data at scheduled intervals, to ensure subject safety.

7.1.1 Patient Data Available

Sixty-one (61) patients were enrolled in the study. Results are presented on all patients through 30 day follow-up. Data is presented for the 48 patients who have reached 6 month follow-up. Adverse events are reported for all patients.

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Table 4. Summary of Patient Data Available

Visit Type	Patient Data Available*	Percent of Total (N=61)
Pre-procedure	61	100%
Procedure	61	100%
Discharge	61	100%
30-day Follow-up	61	100%
3-month Follow-up	54	88.5%
6-month Clinical Follow-up	48	78.7%
6-month Angiogram	42	68.9%

Table 5. Patient Demographics: Age Sex, and Neurological History

Patient Characteristics	
Age (years) [1] Mean ± SD Median Range (min, max)	 63.4 ± 9.8 64 (37, 80)
Male	80.3%
Transient Ischemic Attack	68.9% (42/61)
Stroke	60.7% (37/61)
Other Neurological Disease currently being treated or requiring treatment [2]	3.3% (2/61)

1) Data available through Age statistics based on 58 patients
2) Back injury in one patient, causing back and right leg pain. Bladder dysfunction, described by the investigational site as attributable to neurologic deficit, in one patient.

Table 6 Medical History: Cardiac

Cardiac Risk Factor	Percent with Risk Factor
Hyper tension	63.9% (39/61)
CAD Intervention	13.1% (8/61)
Angina	11.5% (7/61)
Myocardial Infarction	11.5% (7/61)
Arrhythmia	3.3% (2/61)
Atrial Fibrillation	3.3% (2/61)
Other Cardiac [1]	3.3% (2/61)
Patent Foramen Ovale	3.3% (2/61)
Congestive Heart Failure	1.6% (1/61)
Surgical Intervention Planned [2]	1.6% (1/61)

1) Aortic valve replacement in one patient, mild mitral valve insufficiency
2) Cardiac catheterization

Table 7. Medical History: Other

Risk Factors	Percent with Risk Factor
Hypercholesterolemia	54.1% (33/61)
Smoking (current or former)	52.5% (32/61)
Diabetes	32.8% (20/61)
Hereditary or Racial Risk	18.0% (11/61)
Pulmonary Disease: Other*	13.1% (8/61)
Cancer	6.6% (4/61)
Other Significant Risk Factors	4.9% (3/61)
Pulmonary Disease: COPD	4.9% (3/61)
Substance Abuse	4.9% (3/61)
GI Bleed	1.6% (1/61)

*pulmonary cancer, asbestos exposure, sleep apnea, emphysema, possible tuberculosis, and asthma (two)

Baseline lesion locations are listed in Table 8. Of the 61 subjects, six (6) lesions were in the vertebral ostium and 12 in the pre-PICA region of the vertebral artery. These two lesion types were classified as extracranial. Thus, there were 43/61 (70.5%) intracranial lesions, and 18/61 (29.5%) extracranial vertebral lesions.

Table 8. Primary Lesion Location

Primary Lesion Location	# Patients	% of Total (N=61)
Intracranial		
Basilar – proximal	11	18.0%
Basilar – mid	6	9.8%
Internal Carotid – Cavernous	7	11.5%
Intracranial Vertebral – post PICA	5	8.2%
Internal Carotid – Supraclinoid	6	9.8%
Middle Cerebral	5	8.2%
Internal Carotid – Petrous	2	3.3%
Posterior Cerebral	1	1.6%
Total Intracranial	43	70.5%
Extracranial		
Extracranial Vertebral – pre PICA	12	19.7%
Extracranial Vertebral Ostium	6	9.8%
Total Extracranial	18	29.5%

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7.1.2 Primary Endpoints

The primary endpoints for safety are clinical outcome at 30 days (composite stroke and death), and clinical and angiographic outcome at 6 months. Clinical outcome data is reported for the combined patient population of extracranial vertebral and intracranial lesions.

Table 9. Primary Endpoints

Primary Endpoints	(N=61)	
	# Patients	% Incidence
Death and Stroke (composite) at 30 days	4	6.6%
Non-Fatal Stroke at 30 days[1]	4	6.6%
Major stroke	3	4.9%
Minor stroke	1	1.7%
Death at 30 days	0	0%
Death and Stroke (composite) > 30 days	8	13.2%
Non-Fatal Stroke > 30 days	4	6.6%
Major stroke	1[4]	1.7%
Minor stroke	3	4.9%
Death > 30 days	4[5]	6.6%
Acute Success Measures		
Stent Success[2]	58	95.1%
Procedure Success[3]	54	88.5%

1) The Clinical Events Adjudication Committee (CEAC) determined that three of the four strokes were major, and one stroke was minor. The distinction of Major stroke and Minor stroke is based on the NIHSS and/or Modified Rankin Score and/or Barthel Index score at 30 days post-stroke.
2) Stent Success is defined as achieving a final residual stenosis <50% covering an area no longer than the original lesion. Results are based on Core Lab measurements for fifty-three (53) patients and on investigator measurements for the patients for whom Core Lab data is not available.
3) Procedure Success is achieved if there was Stent Success and no death or stroke prior to discharge.
4) This patient later died
5) Two (2) patients had non-fatal major strokes within 30 days of treatment, one (1) patient died of metastatic pancreatic cancer at one year post procedure, one (1) patient suffered a major stroke at one year post-procedure.

7.1.3 Secondary Endpoints

The secondary endpoints include access site complications requiring treatment, angiographic evaluation of the treated segment at six months, and ipsilateral (same territory) stroke at 12 months.

Access Site Complications: There was one access site infection that required treatment, for an incidence rate of 1.6% (1/61).

Angiographic Evaluation at 6 months: Forty-eight (48) patients have completed their six month follow-up. The minimum lumen diameter increased from a mean of 1.00mm at pre-procedure, to a mean of 1.64mm. The percent stenosis decreased from a mean of 69.9% pre-procedure, to a mean of 50.6% at six months. Eighteen (18) patients had stenoses >50% at 6 months, and seven of these (38.9%) were symptomatic, while 11 (61.1%) were asymptomatic.

Ipsilateral stroke at 12 months: The mean follow-up was 216 days , with a minimum and maximum follow-up of 2 and 367 days, respectively. Within this follow-up period, there were four (4) procedure-related strokes; three of these strokes were major and ipsilateral, and one was minor and contralateral. Four (4) strokes occurred after 30 days. Three of these strokes were adjudicated as ipsilateral and minor. The fourth stroke is pending adjudication, and will be assumed to be ipsilateral for the purpose of this analysis.

Table 10. Lesion Characteristics

This data compares independent angiographic core laboratory measurements of lesion characteristics pre-procedure, post-procedure, and at 180 days (6 months) for the combined patient group with extracranial vertebral and intracranial lesions. Subgroup analysis is provided for intracranial lesions only.

Parameter	Baseline [1]		Post-Procedure [1]		6 Months	
	All Vessels (N=60)	Intracranial Only (N=42)	All Vessels (N=60)	Intracranial Only (N=42)	All Vessels (N=42) [7]	Intracranial Only (N=27)
Lesion Length (mm)[2]						
Mean ± SD	5.10 ± 1.91	5.15 ± 1.91				
Median	4.80	4.85				
Range (min, max)	(1.5, 9.9)	(1.5, 9.9)				
Reference Vessel Diameter (mm)						
Mean ± SD	3.29 ± 0.70	3.29 ± 0.74	3.32 ± 0.68	3.30 ± 0.71	3.30 ± 0.61	3.29 ± 0.63
Median	3.30	3.35	3.35	3.40	3.35	3.30
Range (min, max)	(1.7, 4.7)	(1.7, 4.6)	(1.9, 5.0)	(1.9, 4.7)	(2.0, 4.4)	(2.0, 4.4)
MLD at Stenosis (mm)						
Mean ± SD	1.00 ± 0.46	0.95 ± 0.45	2.63 ± 0.72	2.62 ± 0.69	1.64 ± 0.94	1.90 ± 0.98
Median	1.00	0.90	2.50	2.50	1.65	1.80
Range (min, max)	(0.0, 2.3)	(0.0, 2.0)	(1.4, 5.1)	(1.5, 4.2)	(0.0, 4.2)	(0.4, 4.2)
Gain in MDL from Baseline (mm) [3][6]						
Mean ± SD			1.62 ± 0.75	1.68 ± 0.72	1.5 ± 0.9	1.89 ± 0.1
Median			1.60	1.75	1.4	1.8
Range (min, max)			(0.1, 3.7)	(0.5, 3.7)	(-1.3, 2.5)	(-0.5, 3.7)
Percent Stenosis						
Mean ± SD	69.9% ± 12.41	71.1% ± 13.08	20.3% ± 15.38	19.7% ± 15.66	50.6% ± 25.6	43.4% ± 24.1
Median	70.2%	70.7%	16.67%	16.24%	44.8%	42.4%
Range (min, max)	(42%[4],100%)	(42%[4], 100%)	(-9.1%, 56.3%)	(-9.1%, 50.0%)	(0%, 100%)	(0.0%, 84.4%)
Change in % Stenosis from Baseline[5][6]						
Mean ± SD			+49.6% ± 20.44	+51.3% ±19.79	+17.1% ± 28.0	+26.4% ± 26.7%
Median			46.75%	52.45%	44.8%	42.4%
Range (min, max)			(3.1%, 100%)	(17.9%, 100%)	(+63.5%, -50%)	(-15.3%, 90.2%)
# >50% Stenosis	57 / 60 (95%)	40/42 (95%)	1 / 60 (1.6%)	1 / 42 (2.6%)	18 / 42 (42.9%)	10 / 27 (37%)

1) All data is from core lab when available. For seven patients without core lab data, the physician measurements were used.
2) Twenty-one (21) of 53 lesions measured by the core lab exceeded 5mm length pre-procedure. In all instances the investigator had measured the lesion as ≤5mm pre- procedure, qualifying the patients for study enrollment. Sixteen (16) of these lesions were intracranial.
3) Acute gain is defined as the difference in MLD between the pre- and post-procedure. A positive number indicates that the lumen is larger after the procedure.
4) The core lab measured three lesions as <50% stenosis pre-procedure. Investigators measured these lesions as 50%, 53%, and 63%, respectively, qualifying the patients for study enrollment. Two of these were intracranial lesions.
5) Change is pre-treatment value minus post-treatment value, therefore a positive number denotes a decrease in percentage stenosis.
6) A negative number for MDL or % stenosis indicates that the lumen diameter or % stenosis have become larger over time.
7) Four of 6 patients with lesions of the extracranial vertebral ostium had asymptomatic total occlusion at follow-up angiography.

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8.0 INDIVIDUALIZATION OF TREATMENT

The risks and benefits described above should be considered for each patient before use of the NEUROLINK Stent and Delivery Catheter.

9.0 PATIENT COUNSELING INFORMATION

Patients must be advised of the risks and benefits of treatment with the NEUROLINK System compared with other treatment options. Patients should be informed that there is no data to support the effectiveness of the NEUROLINK System for the treatment of intracranial atherosclerosis.

10.0 HOW SUPPLIED

STERILE: This device is sterilized with ethylene oxide gas. It is intended for single use only. Non-pyrogenic. Do not use if the package is open or damaged.

CONTENTS: One (1) NEUROLINK® Stent & Delivery Catheter with re-grooming sheath, One (1) NEUROLINK® Stent & Delivery Catheter Compliance Card, One (1) Instructions for Use, One (1) Patient Brochure Package.

STORAGE: Store in a cool, dry, dark place.

11.0 CLINICIAN USE INFORMATION/DIRECTIONS FOR USE

11.1 Inspection Prior to Use

Prior to using the NEUROLINK® Stent & Delivery Catheter, carefully remove the system from its package and inspect for bends, kinks, and other damage. Take care to avoid unnecessary handling, which may damage the system. Verify that the Stent does not extend beyond the radiopaque balloon markers. Do not use if any defects are noted.

11.2 Materials Required

Quantity	Material
As required	Appropriate guiding catheter(s). See Table 1 Device Specifications
2 – 3	10-20cc syringes
1,000u / 500cc	Sterile Heparinized Normal Saline (HepNS)
1	0.014 inch x 175cm (minimum length) guide wire
1	Rotating hemostatic valve with 0.096 inch minimum inner diameter
As required	60% contrast diluted 1:1 with normal saline
1	Inflation device
1	Three-way stopcock
1	Guide wire torque device
1	Guide wire introducer

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11.3 Preparation

11.3.1 Guide Wire Lumen Flush

Step	Action
1	Remove the protective cover from the tip of the Delivery System.
2	Flush the guide wire lumen with sterile HepNS until fluid exits the Delivery System tip.
3	Verify that the Stent is positioned between the proximal and distal balloon markers.

11.3.2 Delivery Catheter Preparation

Step	Action
1	Prepare inflation device or syringe with diluted contrast medium.
2	Attach inflation device or syringe to stopcock; attach to inflation port.
3	With the tip down, orient the Delivery System vertically.
4	Open the stopcock to the Delivery System; pull negative on the inflation device or syringe for 30 seconds to evacuate air from the Delivery Catheter. Release the inflation device or syringe to neutral pressure for contrast medium fill.
5	Close the stopcock to the Delivery System; purge the inflation device or syringe of all air.
6	Repeat steps 3 through 5 until all air is evacuated. NOTE: If air is seen in shaft, repeat Delivery System Preparation steps 3 through 5 to prevent uneven Stent expansion.
7	If a syringe was used for Delivery Catheter preparation, remove it and attach an inflation device prepared with contrast medium to the stopcock.
8	Open Stopcock to Delivery System.
9	Leave on neutral pressure.
10	Submerge the Stent & Delivery Catheter in sterile HepNS to hydrate the hydrophilic coating.

11.3.3 Delivery Procedure

Step	Action
1	Prepare the vascular access site according to standard practice.
2	If required, pre-dilate the lesion with the appropriate size Balloon Dilatation Catheter to permit unobstructed passage of the Stent & Delivery Catheter. Refer to Instructions for Use for the Balloon Dilatation Catheter.
3	Backload the distal tip of the Stent and Delivery Catheter onto the proximal portion of the guide wire. Open the rotating hemostatic valve (located on the guiding catheter) as wide as possible while maintaining the guide wire position across the target lesion. Advance the Stent and Delivery Catheter over the guide wire to the target lesion.
4	Utilize the radiopaque balloon markers to position the Stent across the lesion. Perform angiography as needed to confirm the Stent position.
5	Tighten the rotating hemostatic valve. The Stent is now ready to be deployed.

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11.3.4 Stent Deployment Procedure

Step	Action
1	CAUTION: Refer to the product label for *in vitro* Stent inner diameter and RBP. Do not exceed the RBP indicated on the compliance card. Do not expand the Stent beyond 5.0 mm inner diameter.
2	Deploy the Stent slowly by pressurizing the Delivery Catheter in 2.0atm increments, every 5 seconds until the Stent is completely expanded. Maintain this pressure for 30 seconds. If necessary, the Delivery Catheter can be re-pressurized or further pressurized to assure complete apposition of the Stent to the vessel wall.
3	If the deployed Stent size is still inadequate with respect to reference vessel diameter, a BDC in a larger diameter may be used to further expand the Stent. If the initial angiographic appearance is sub-optimal, the Stent may be further expanded using the BDC. If this is required, the stented segment should be carefully re-crossed with a prolapsed guide wire to avoid disrupting the Stent geometry. Deployed Stents should not be left under-dilated.
4	Deflate the Delivery Catheter by pulling negative on the inflation device for 30 seconds.

11.3.5 Delivery System Removal Procedure

Step	Action
1	Ensure that the Delivery Catheter is fully deflated. Release the inflation device to neutral pressure.
2	Fully open the rotating hemostatic valve.
3	While maintaining the guide wire position and neutral pressure on the inflation device, withdraw the Delivery System.
4	Tighten the rotating hemostatic valve.
5	Repeat angiography to assess the stented area to confirm apposition of the Stent to the vessel wall. If necessary, perform post-dilatation to ensure that the Stent is fully expanded.

12.0 PATIENT'S MANUAL

In addition to this Instructions for Use booklet, patient-specific information is available on the NEUROLINK Stent and Delivery Catheter which includes:

- A Patient Implant Card that includes both patient and NEUROLINK Stent specific information. All patients will be expected to keep this card in their possession at all times for procedure/Stent identification.
- A Patient Teaching Guide which includes information on Guidant Corporation and the implant procedure.

13.0 PATENTS

This product and its use are protected under one or more of the following patents. United States,

5,391,172; B1 5,421,955; 5,470,313; 5,514,154; 5,554,121; 5,569,295; 5,603,721; 5,645,560; 5,649,952; 5,728,158; 5,759,192; 5,780,807; 5,782,855; 5,843,116; 6,017,364; 6,056,776 Other U.S. patents pending. Foreign patents issued and pending.

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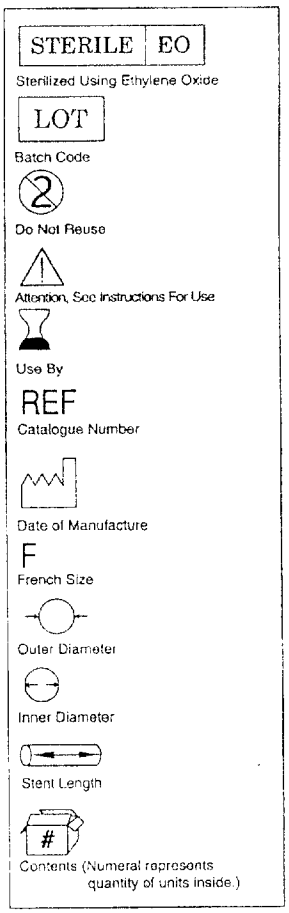
Graphical Symbols for Medical Device Labeling



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REVISED DRAFT

Revision 5 August 9, 2002

TITLE: IFU, NEUROLINK® BALLOON DILATATION CATHETER

This revision is for filing, registration or translation purposes only.

This version may not be purchased.

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GUIDANT

NEUROLINK® BALLOON DILATATION CATHETER

HUMANITARIAN DEVICE: The Guidant NEUROLINK Balloon Dilatation Catheter is a component of the NEUROLINK System. The Guidant NEUROLINK System is authorized by Federal law for use in treatment of recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 mm to 4.5 mm in diameter with >50% stenosis and that are accessible to the stent system.

The effectiveness of this device for this use has not been demonstrated.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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1.0 DEVICE DESCRIPTION

The NEUROLINK® System is comprised of the NEUROLINK® Balloon Dilatation Catheter and the NEUROLINK® Stent & Delivery Catheter. The Balloon Dilatation Catheter is an over-the-wire, co-axial catheter design, with the Balloon located at the distal end. The distal shaft of the catheter is coated with a hydrophilic coating that is activated when hydrated. Proximal and distal radiopaque markers are positioned within the Balloon to demarcate the shoulders of the Balloon, and are used to facilitate accurate positioning of the Balloon within an artery.

The side arm of the two-arm adapter at the proximal end of the Balloon Catheter provides access to the Balloon inflation lumen and has a luer-lock fitting for the connection of an inflation device. The central arm of the two-arm adapter provides access to the guide wire lumen. The Balloon is designed to inflate to a specific diameter and length at a specified pressure. The Balloon is available in a range of diameters from 2.0 mm to 5.0 mm, in 0.5 mm increments. The Balloon is available in a 10 mm length.

Table 1. *In vitro* Device Specifications

Balloon Diameter (mm) [1]	Balloon Length (mm) [1]	Minimum Guiding Catheter Compatibility[2]	Rated Burst Pressure – RBP (atm)
2.0	10	6F / 0.062"/1.57 mm	10
2.5	10	6F / 0.062"/1.57 mm	10
3.0	10	6F / 0.062"/1.57 mm	10
3.5	10	6F / 0.062"/1.57 mm	10
4.0	10	6F / 0.062"/1.57 mm	10
4.5	10	6F / 0.062"/1.57 mm	10
5.0	10	6F / 0.062"/1.57 mm	10

1) Refer to the compliance chart for accurate sizing information.
2) Refer to the individual manufacturer specifications to confirm the guide catheter inner diameter (F) equivalent.

Table 2. Device Specifications for the NEUROLINK® Balloon Dilatation Catheter

Product	Balloon Diameter(s) (mm)	Balloon Length (mm)	Crossing Profile (inches)
NEUROLINK® Balloon Dilatation Catheter Inflation Pressures RBP 10atm Nom. 3.5atm–10atm	2.0 2.5 3.0 3.5 4.0 4.5 5.0	10	0.034" 0.038" 0.040" 0.044" 0.045" 0.049" 0.053"

2.0 INTENDED USE/INDICATIONS

The NEUROLINK Balloon Dilatation Catheter is used in conjunction with the NEUROLINK Stent and Delivery Catheter in the treatment of recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 mm to 4.5 mm in diameter with ≥50% stenosis and that are accessible to the stent system.

3.0 CONTRAINDICATIONS

The Balloon Dilatation Catheter is contraindicated for use in:

- Lesions that are highly calcified or otherwise could prevent access or appropriate expansion of the Stent.
- Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated.

4.0 WARNINGS

- The Balloon Dilatation Catheter should be used only by physicians with interventional training and thorough knowledge of angiographic techniques.

5.0 PRECAUTIONS

For single use only. Do not resterilize or reuse the device. Note product "Use By" date.

- Follow the Balloon Dilatation Catheter preparation instructions carefully as described in Section 11.3, Preparation. Do not prepare or pre-inflate the Balloon Dilatation Catheter prior to its use other than as directed.
- Use only the recommended balloon inflation medium (see Section 11.2, Materials Required). Do not use air or any gaseous medium to inflate the balloon.
- The Balloon Dilatation Catheter should not be used in conjunction with stents other than the NEUROLINK Stent.
- Do not exceed the Rated Burst Pressure specified on the product label. Balloon pressure must be monitored during inflation. Use of pressures higher than that specified on the product label may result in a ruptured balloon with possible intimal damage, vessel dissection, and/or vessel rupture.
- To avoid disrupting Stent geometry or its position within the vessel, care must be exercised when crossing a newly deployed Stent with a guide wire or the Balloon Dilatation Catheter.

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6.0 ADVERSE EVENTS

6.1 Potential Adverse Events

Adverse events listed below may be associated with the use of the NEUROLINK Balloon Dilatation Catheter in intracranial arteries.

Acute myocardial infarction

Death

Dissection

Drug reactions to anti-platelet or anticoagulant agents or contrast medium

Distal emboli (air, tissue or thrombotic emboli)

Fistula

Hemorrhage requiring transfusion

Hypotension/hypertension

Infection and pain at access site

Intracranial hemorrhage

Ischemia, cerebral

Pseudoaneurysm, femoral

Restenosis of stented segment

Spasm, vessel

Stent deformation

Stent embolization

Stent thrombosis/occlusion

Stroke/cerebrovascular accident

Total occlusion of an intracranial artery

Vessel perforation or rupture

Vessel spasm

6.2 Observed Adverse Events

Sixty-one (61) patients have been enrolled in a multi-center, prospective, non-randomized, international clinical trial to evaluate the safety and feasibility of the NEUROLINK System for the treatment of symptomatic atherosclerotic lesions in extracranial vertebral and intracranial arteries. Adverse events were recorded for the procedure and for a mean follow-up of 216 days on the 61 patients. Twenty-four types of adverse events were recorded for 29 of 61 patients (47.5%). Twenty (20) patients had one adverse event, five (5) patients had two events, three (3) patients had three events, and one (1) patient had four events. Twenty (20) adverse events were related to the device and/or procedure; 18 events were not related, and the relationship is pending review in five (5) events. For one (1) event, additional information is pending. Table 4 summarizes the observed adverse events.

Table 3 identifies the adverse events observed in the clinical study conducted to evaluate the safety and probable benefit of the NEUROLINK® System. Sixty-one patients were enrolled in the study and information is presented on all patients through 30 days and on 48 patients who have reached the 6 month follow-up time point (See Section 7, Clinical Experience).

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Table 3. Adverse Events

Event	# (%) (N=61)	Time of Occurrence			Device / Procedure Related		
		Proced[1]	<30 days	>30 days	Yes	No	Pending[2]
Stroke	8 (13.1%)	4[3, 4]	0	4[5]	5	2[6,7]	1
TIA	4 (6.6%)	0	1	3	3[8]	1[9]	0
Access Site Infection	1 (1.6%)	0	1	0	1	0	0
Ankle Swelling	1 (1.6%)	0	0	1	0	1	0
Arterial Dissection	2 (3.3%)	2	0	0	2	0	0
Atrial Fibrillation	1 (1.6%)	0	0	1	0	1	0
Bradycardia	1 (1.6%)	1	0	0	1	0	0
Cancer (Pancreatic)	2 (3.3%)	0	0	2	0	0	2
Carotid Cavernous Fistula	1 (1.6%)	1[10]	0	0	1	0	0
Congestive Heart Failure	2 (3.3%)	0	1[11]	1	0	2	0
Diabetes Mellitus (new)	1 (1.6%)	0	0	1	0	1	0
Dysesthesia	2 (3.3%)	0	0	2	0	2	0
Ecchymosis (eye)	1 (1.6%)	1	0	0	1	0	0
Fractured Spine	1 (1.6%)	0	0	1	0	1	0
Kidney Stones	1 (1.6%)	0	0	1	0	1	0
Nerve Paresis (6^{th})	1 (1.6%)	1	0	0	1	0	0
Neurologic Symptoms	2 (3.3%)	0	0	2	1[12]	0	1[13]
Peripheral Vascular Disease	1 (1.6%)	0	0	1	0	1	0
Rehospitalized for revascularization of asymptomatic stenosis	2 (3.3%)	0	0	2	2[14, 15]	0	0
Stent Occlusion (Acute)	1 (1.6%)	1[16]	0	0	1	0	0
Syncope	2 (3.3%)	0	0	2	0	1	1
Thrombocytopenia	1 (1.6%)	0	1	0	0	1	0
Vertebral Artery Bypass	1 (1.6%)	0	0	1	1	0	0
Vertigo	3 (4.9%)	0	0	3	0	3	0

1) 'Procedural' means that the event occurred at the time of the procedure or within the same hospitalization but not in excess of 30 days within the same hospitalization
2) Event is pending adjudication by the Clinical Events Adjudication Committee
3) Three strokes were adjudicated as major in severity, one as minor
4) Two of these patients later died
5) One of these patients later died
6) No Stent was implanted in one of these patients. Stroke occurred five months post-procedure and is adjudicated as not related to the test device or procedure
7) Adjudicated as not related to the test device or procedure, minor and ipsilateral, due to local microvascular thrombosis
8) One of these TIAs was previously reported as, "possible re-emergence of stroke symptoms". CEAC adjudicated event as "TIA, probably related to test device and procedure".
9) Per investigator, symptoms occurred after six-month angiogram and are not related to the test device, but are probably related to pre-existing condition or may be reaction to contrast dye used for the six-month angiogram.
10) Occurred at the time of the procedure, but did not require treatment until after 30 days
11) Exacerbation of existing congestive heart failure at 20 days post-procedure
12) Symptoms consistent with malperfusion syndrome related to restenosis of the target lesion. Stroke and TIA ruled out. Target lesion revascularization by balloon angioplasty.
13) Symptoms of facial droop and incontinence which resolved in 15 minutes. Ruled out stroke and TIA.
14) Six-month angiogram demonstrated 71% in-stent restenosis; neurologic exam and stroke scale scores unchanged. Patient anxious and requested treatment. Target lesion revascularization using PTA, with residual stenosis of 46%. Follow-up unremarkable.
15) Patient asymptomatic but restenosis determined to be "hemodynamically relevant" therefore target lesion revascularization performed with PTA.
16) Lytic (10mg rt-PA) was administered and occlusion resolved with no clinical sequelae.

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7.0 CLINICAL EXPERIENCE

7.1 SSYLVIA: Stenting of SYmptomatic atherosclerotic Lesions in the Vertebral and Intracranial Arteries

The NEUROLINK® System was designed for the treatment of recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy. The SSYLVIA clinical study is a prospective, non-randomized, multi-center, international study and is ongoing. The objective of the study is to evaluate the safety and feasibility of the NEUROLINK System for the treatment of symptomatic atherosclerotic lesions in the extracranial vertebral and intracranial arteries. Patients were eligible for participation in the study if they were symptomatic (previous stroke or TIA) due to an angiographically demonstrated, discrete stenosis >50% and ≤5mm in length in an extracranial vertebral or intracranial artery between 2.5mm and 4.5mm in diameter. The clinical study evaluated stent use in a broader patient population than that characterized in the Humanitarian Use Device (HUD) designation.

All patients were required to receive an antiplatelet regimen beginning at least 48 hours prior to the procedure. This consisted of aspirin (minimum 100mg twice daily) and Clopidogrel (75mg twice daily). Heparin was administered during the Stent implantation procedure to maintain the activated clotting time (ACT) at a therapeutic level of 200 to 300 seconds.

The NEUROLINK® Balloon Dilatation Catheter could be used to predilate the lesion to facilitate access by the NEUROLINK Stent and Delivery Catheter. Both the Balloon and Stent were sized in a 1:1 ratio to the smaller of the diameters of the vessel proximal or distal to the lesion. Post-dilatation with either the Delivery Catheter or the Balloon Dilatation Catheter could be used to optimize Stent apposition and residual stenosis. Post-procedure, dual antiplatelet therapy was required. This consisted of aspirin daily for a minimum of one (1) year, plus Clopidogrel for a minimum of four (4) weeks. Device and procedural safety were determined by analyzing acute and 30-day individual endpoints, and all adverse events. All primary endpoints were analyzed on an intent-to-treat basis.

The primary endpoints for safety for this study are: Composite Death and Stroke at 30 days, Death at 30 days, and Non-Fatal stroke at 30 days. All patients are required independent neurologic examinations (performed by the non-operator stroke neurologist investigator) at one, three, six, and 12 months. Angiographic assessment of the stented lesion is required at six months. All procedure and follow-up angiograms are analyzed by an independent Angiographic Core Laboratory. Major clinical events are adjudicated by an independent Clinical Events Adjudication Committee. The Data Safety Monitoring Board (DSMB) is responsible for review of the cumulative safety data at scheduled intervals, to ensure subject safety.

7.1.1 Patient Data Available

Sixty-one (61) patients were enrolled in the study. Results are presented on all patients through 30 day follow-up. Data is presented for the 48 patients who have reached 6 month follow-up. Adverse events are reported for all patients.

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Table 4. Summary of Patient Data Available

Visit Type	Patient Data Available*	Percent of Total (N=61)
Pre-procedure	61	100%
Procedure	61	100%
Discharge	61	100%
30-day Follow-up	61	100%
3-month Follow-up	54	88.5%
6-month Clinical Follow-up	48	78.7%
6-month Angiogram	42	68.9%

Table 5. Patient Demographics: Age Sex, and Neurological History

Patient Characteristics	
Age (years) [1] Mean ± SD Median Range (min, max)	 63.4 ± 9.8 64 (37, 80)
Male	80.3%
Transient Ischemic Attack	68.9% (42/61)
Stroke	60.7% (37/61)
Other Neurological Disease currently being treated or requiring treatment [2]	3.3% (2/61)

1) Data available through Age statistics based on 58 patients
2) Back injury in one patient, causing back and right leg pain. Bladder dysfunction, described by the investigational site as attributable to neurologic deficit, in one patient.

Table 6 Medical History: Cardiac

Cardiac Risk Factor	Percent with Risk Factor
Hyper tension	63.9% (39/61)
CAD Intervention	13.1% (8/61)
Angina	11.5.% (7/61)
Myocardial Infarction	11.5% (7/61)
Arrhythmia	3.3% (2/61)
Atrial Fibrillation	3.3% (2/61)
Other Cardiac[1]	3.3% (2/61)
Patent Foramen Ovale	3.3% (2/61)
Congestive Heart Failure	1.6% (1/61)
Surgical Intervention Planned[2]	1.6% (1/61)

1) Aortic valve replacement in one patient, mild mitral valve insufficiency
2) Cardiac catheterization

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Table 7. Medical History: Other

Risk Factors	Percent with Risk Factor
Hypercholesterolemia	54.1% (33/61)
Smoking (current or former)	52.5% (32/61)
Diabetes	32.8% (20/61)
Hereditary or Racial Risk	18.0% (11/61)
Pulmonary Disease: Other*	13.1% (8/61)
Cancer	6.6% (4/61)
Other Significant Risk Factors	4.9% (3/61)
Pulmonary Disease: COPD	4.9% (3/61)
Substance Abuse	4.9% (3/61)
GI Bleed	1.6% (1/61)

*pulmonary cancer, asbestos exposure, sleep apnea, emphysema, possible tuberculosis, and asthma (two)

Baseline lesion locations are listed in Table 8. Of the 61 subjects, six (6) lesions were in the vertebral ostium and 12 in the pre-PICA region of the vertebral artery. These two lesion types were classified as extracranial. Thus, there were 43/61 (70.5%) intracranial lesions, and 18/61 (29.5%) extracranial vertebral lesions.

Table 8. Primary Lesion Location

Primary Lesion Location	# Patients	% of Total (N=61)
Intracranial		
Basilar – proximal	11	18.0%
Basilar – mid	6	9.8%
Internal Carotid – Cavernous	7	11.5%
Intracranial Vertebral – post PICA	5	8.2%
Internal Carotid – Supraclinoid	6	9.8%
Middle Cerebral	5	8.2%
Internal Carotid – Petrous	2	3.3%
Posterior Cerebral	1	1.6%
Total Intracranial	43	70.5%
Extracranial		
Extracranial Vertebral – pre PICA	12	19.7%
Extracranial Vertebral Ostium	6	9.8%
Total Extracranial	18	29.5%

7.1.2 Primary Endpoints

The primary endpoints for safety are clinical outcome at 30 days (composite stroke and death), and clinical and angiographic outcome at 6 months. Clinical outcome data is reported for the combined patient population of extracranial vertebral and intracranial lesions.

Table 9. Primary Endpoints

Primary Endpoints	(N=61)	
	# Patients	% Incidence
Death and Stroke (composite) at 30 days	4	6.6%
Non-Fatal Stroke at 30 days[1]	4	6.6%
Major stroke	3	4.9%
Minor stroke	1	1.7%
Death at 30 days	0	0%
Death and Stroke (composite) > 30 days	8	13.2%
Non-Fatal Stroke > 30 days	4	6.6%
Major stroke	1[4]	1.7%
Minor stroke	3	4.9%
Death > 30 days	4[5]	6.6%
Acute Success Measures		
Stent Success[2]	58	95.1%
Procedure Success[3]	54	88.5%

1) The Clinical Events Adjudication Committee (CEAC) determined that three of the four strokes were major, and one stroke was minor. The distinction of Major stroke and Minor stroke is based on the NIHSS and/or Modified Rankin Score and/or Barthel Index score at 30 days post-stroke.
2) Stent Success is defined as achieving a final residual stenosis <50% covering an area no longer than the original lesion. Results are based on Core Lab measurements for fifty-three (53) patients and on investigator measurements for the patients for whom Core Lab data is not available.
3) Procedure Success is achieved if there was Stent Success and no death or stroke prior to discharge.
4) This patient later died
5) Two (2) patients had non-fatal major strokes within 30 days of treatment, one (1) patient died of metastatic pancreatic cancer at one year post procedure, one (1) patient suffered a major stroke at one year post-procedure.

7.1.3 Secondary Endpoints

The secondary endpoints include access site complications requiring treatment, angiographic evaluation of the treated segment at six months, and ipsilateral (same territory) stroke at 12 months.

Access Site Complications: There was one access site infection that required treatment, for an incidence rate of 1.6% (1/61).

Angiographic Evaluation at 6 months: Forty-eight (48) patients have completed their six month follow-up. The minimum lumen diameter increased from a mean of 1.00mm at pre-procedure, to a mean of 1.64mm. The percent stenosis decreased from a mean of 69.9% pre-procedure, to a mean of 50.6% at six months. Eighteen (18) patients had stenoses >50% at 6 months, and seven of these (38.9%) were symptomatic, while 11 (61.1%) were asymptomatic.

Ipsilateral stroke at 12 months: The mean follow-up was 216 days , with a minimum and maximum follow-up of 2 and 367 days, respectively. Within this follow-up period, there were four (4) procedure-related strokes; three of these strokes were major and ipsilateral, and one was minor and contralateral. Four (4) strokes occurred after 30 days. Three of these strokes were adjudicated as ipsilateral and minor. The fourth stroke is pending adjudication, and will be assumed to be ipsilateral for the purpose of this analysis.

Table 10. Lesion Characteristics

This data compares independent angiographic core laboratory measurements of lesion characteristics pre-procedure, post-procedure, and at 180 days (6 months) for the combined patient group with extracranial vertebral and intracranial lesions. Subgroup analysis is provided for intracranial lesions only.

Parameter	Baseline [1]		Post-Procedure [1]		6 Months	
	All Vessels (N=60)	Intracranial Only (N=42)	All Vessels (N=60)	Intracranial Only (N=42)	All Vessels (N=42) [7]	Intracranial Only (N=27)
Lesion Length (mm) [2] Mean ± SD Median Range (min, max)	5.10 ± 1.91 4.80 (1.5, 9.9)	5.15 ± 1.91 4.85 (1.5, 9.9)				
Reference Vessel Diameter (mm) Mean ± SD Median Range (min, max)	3.29 ± 0.70 3.30 (1.7, 4.7)	3.29 ± 0.74 3.35 (1.7, 4.6)	3.32 ± 0.68 3.35 (1.9, 5.0)	3.30 ± 0.71 3.40 (1.9, 4.7)	3.30 ± 0.61 3.35 (2.0, 4.4)	3.29 ± 0.65 3.30 (2.0, 4.4)
MLD at Stenosis (mm) Mean ± SD Median Range (min, max)	1.00 ± 0.46 1.00 (0.0, 2.3)	0.95 ± 0.45 0.90 (0.0, 2.0)	2.63 ± 0.72 2.50 (1.4, 5.1)	2.62 ± 0.69 2.50 (1.5, 4.2)	1.64 ± 0.94 1.65 (0.0, 4.2)	1.90 ± 0.98 1.80 (0.4, 4.2)
Gain in MDL from Baseline (mm) [3][5] Mean ± SD Median Range (min, max)			1.62 ± 0.75 1.60 (0.1, 3.7)	1.68 ± 0.72 1.75 (0.5, 3.7)	1.5 ± 0.9 1.4 (-1.3, 2.5)	1.89 ± 0.1 1.8 (-0.5, 3.7)
Percent Stenosis Mean ± SD Median Range (min, max)	69.9% ± 12.41 70.2% (42%[4], 100%)	71.1% ± 13.08 70.7% (42%[4], 100%)	20.3% ± 15.38 16.67% (-9.1%, 56.3%)	19.7% ± 15.66 16.24% (-9.1%, 50.0%)	50.6% ± 25.6 44.8% (0%, 100%)	43.4% ± 24.1 42.4% (0.0%, 85.3%)
Change in % Stenosis from Baseline [5][6] Mean ± SD Median Range (min, max)			+49.6% ± 20.44 46.75% (3.1%, 100%)	+51.3% ±19.79 52.45% (17.9%, 100%)	+17.1% ± 28.0 44.8% (+63.5%, -50%)	+26.4% ± 26.7% 42.4% (-15.3%, 90.2%)
# >50% Stenosis	57 / 60 (95%)	40/42 (95%)	1 / 60 (1.6%)	1 / 42 (2.6%)	18 / 42 (42.9%)	10 / 27 (37%)

1) All data is from core lab when available. For seven patients without core lab data, the physician measurements were used.
2) Twenty-one (21) of 53 lesions measured by the core lab exceeded 5mm length pre-procedure. In all instances the investigator had measured the lesion as ≤5mm pre- procedure, qualifying the patients for study enrollment. Sixteen (16) of these lesions were intracranial.
3) Acute gain is defined as the difference in MLD between the pre- and post-procedure. A positive number indicates that the lumen is larger after the procedure.
4) The core lab measured three lesions as <50% stenosis pre-procedure. Investigators measured these lesions as 50%, 53%, and 63%, respectively, qualifying the patients for study enrollment. Two of these were intracranial lesions.
5) Change is pre-treatment value minus post-treatment value, therefore a positive number denotes a decrease in percentage stenosis.
6) A negative number for MDL or % stenosis indicates that the lumen diameter or % stenosis have become larger over time.
7) Four of 6 patients with lesions of the extracranial vertebral ostium had asymptomatic total occlusion at follow-up angiography.

8.0 INDIVIDUALIZATION OF TREATMENT

The risks and benefits described above should be considered for each patient before use of the NEUROLINK Balloon Dilatation Catheter.

9.0 PATIENT COUNSELING INFORMATION

Patients must be advised of the risks and benefits of treatment with the NEUROLINK System compared with other treatment options. Patients should be informed that there is no data to support the effectiveness of the NEUROLINK System for the treatment of intracranial atherosclerosis.

10.0 HOW SUPPLIED

Sterile. This device is sterilized with ethylene oxide gas. It is intended for single use only. Non-pyrogenic. Do not use if the package is open or damaged.

Contents. One (1) NEUROLINK Balloon Dilatation Catheter with regrooming sheath, One (1) NEUROLINK Balloon Dilatation Catheter Compliance Card, One (1) Instructions for Use

Storage. Store in a cool, dry, dark place.

11.0 CLINICIAN USE INFORMATION/DIRECTIONS FOR USE

11.1 Inspection Prior to Use

Prior to using the NEUROLINK® Balloon Dilatation Catheter, carefully remove the system from its package and inspect for bends, kinks, and other damage. Take care to avoid unnecessary handling, which may damage the system. The shaft may kink if not handled carefully. Do not use if any defects are noted.

11.2 Materials Required

Quantity	Material
As required	Appropriate guiding catheter(s). See Table 1 Device Specifications
2 – 3	10-20 cc syringes
1,000u / 500cc	Sterile Heparinized Normal Saline (HepNS)
1	0.014 inch x 175 cm (minimum length) guide wire. If device exchanges are anticipated, a longer length guide wire is recommended.
1	Rotating hemostatic valve with 0.096 inch minimum inner diameter
As required	60% contrast diluted 1:1 with normal saline
1	Inflation device
1	Three-way stopcock
1	Guide wire torque device
1	Guide wire introducer

11.3 Preparation

11.3.1 Guide Wire Lumen Flush

Step	Action
1	Remove the protective cover from the tip of the Balloon Dilatation Catheter.
2	Flush the guide wire lumen with sterile HepNS until fluid exits the Balloon tip.

11.3.2 Balloon Dilatation Catheter Preparation

Step	Action
1	Prepare inflation device or syringe with diluted contrast medium.
2	Attach inflation device or syringe to stopcock; attach to the inflation port of the Balloon.
3	With the tip down, orient the Balloon Dilatation Catheter vertically.
4	Open the stopcock to the Balloon Dilatation Catheter; pull negative on the inflation device or syringe for 30 seconds to evacuate air from the Balloon Dilatation Catheter. Release the inflation device or syringe to neutral pressure for contrast medium fill.
5	Close the stopcock to the Balloon Delivery Catheter; purge the inflation device or syringe of all air.
6	Repeat steps 3 through 5 until all air is evacuated.
7	If a syringe was used for Balloon Dilatation Catheter preparation, remove it and attach an inflation device prepared with contrast medium to the stopcock.
8	Open the Stopcock to Balloon.
9	Leave on neutral pressure.
10	Submerge the Balloon Dilatation Catheter in sterile HepNS to hydrate the hydrophilic coating.

11.3.3 Delivery Procedure

Step	Action
1	Prepare the vascular access site according to standard practice.
2	Backload the distal portion of the Balloon Dilatation Catheter onto the proximal portion of the guide wire. Open the rotating hemostatic valve (located on the guide catheter) as wide as possible while maintaining guide wire position across the target lesion. Advance the Balloon over the guide wire to the target lesion.
3	Utilize the radiopaque balloon markers to position the Balloon across the lesion. Perform angiography as needed to confirm the Balloon position.
5	Tighten the rotating hemostatic valve.

11.3.4 Balloon Deployment Procedure

Step	Action
1	CAUTION: Refer to the product label for *in vitro* Balloon inner diameter and RBP. Do not exceed the RBP indicated on the compliance card.
2	If pre-dilating a lesion, deploy the Balloon slowly by pressurizing the Balloon in 2.0 atm increments, every 5 seconds until satisfactory Balloon diameter is obtained. Maintain this pressure for 30 seconds. If necessary, the Balloon can be re-pressurized or further pressurized to obtain a satisfactory result.
3	If post-dilating a Stent, deploy the Balloon slowly by pressurizing the Balloon in 2.0 atm increments, every 5 seconds until a satisfactory Balloon diameter is obtained. If necessary, the Balloon can be re-pressurized or further pressurized to ensure complete apposition of the Stent to the artery wall.
4	Deflate the Balloon by pulling negative on the inflation device for 30 seconds.

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11.3.5 Balloon Dilatation Catheter Removal Procedure

Step	Action
1	Ensure that the Balloon is fully deflated. Release the inflation device to neutral pressure.
2	Fully open the rotating hemostatic valve.
3	While maintaining the guide wire position and neutral pressure on the inflation device, withdraw the Balloon.
4	Tighten the rotating hemostatic valve.
5	Repeat angiography to assess the stented area to confirm apposition of the Stent to the vessel wall. If necessary, repeat post-dilatation to ensure that the Stent is fully expanded.

12.0 PATENTS

This product and its use are protected by the following patent. United States 5,554,121.

Other U.S. patents pending. Foreign patents issued and pending.

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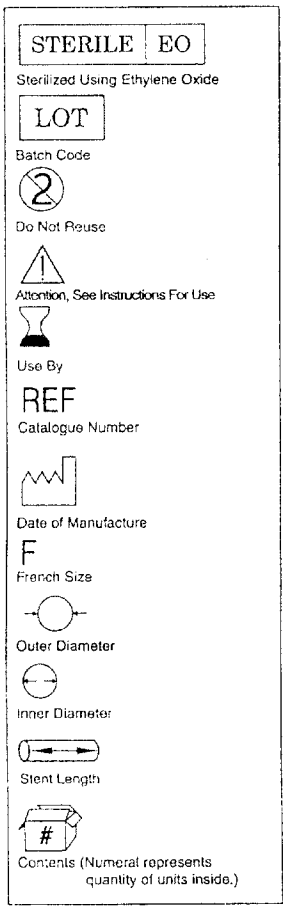
Graphical Symbols for Medical Device Labeling



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A patient's **guide** to STENT IMPLANTATION

GUIDANT CORPORATION

"It's a great time to be alive℠"

August 2002
PPL2034602

Humanitarian Device. Authorized by Federal (U.S.) law for use in the treatment of recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 mm to 4.5 mm in diameter with ≥ 50 % stenosis and that is accessible with the stent System. The effectiveness of this device for this use has not been demonstrated.

This booklet is provided as a service by Guidant Corporation. Guidant is one of the world's largest medical device companies and a leader in cardiovascular and vascular therapeutic device solutions. We are committed to providing high quality medical devices for doctors and patients around the world.

This brochure has been given to you because you have been told by your doctor that further treatment may be necessary for the symptoms you are experiencing. One treatment option may be the NEUROLINK Stent. This brochure provides information about the NEUROLINK Stent and the procedure that may be done to put this stent in the blood vessels in your brain. As you read, you might think of some questions that you would like to discuss in more detail with your doctor or nurse -- you'll find a place in back for your notes.

Guidant Corporation

INTRODUCTION

Table of Contents

Definitions of Medical Terms

We have underlined these words when they appear in the brochure, so that you can refer back to these definitions.

angiogram - x-ray pictures of your blood vessels taken with contrast dye
angiographic suite - a combined x-ray room and operating room
angioplasty - a procedure in which a balloon is used to open the blood vessels
anti-coagulant or antiplatelet – drugs given to slow down the clotting of blood
artery – a kind of blood vessel
atherosclerosis - a collection of fatty deposits on the inside the blood vessel walls. This causes the path for the blood flow to become narrow and hardens the vessel walls
balloon catheter – a thin tube with a balloon on the tip that can be inflated to expand vessel blockages
catheter - a thin tube through which fluids or objects can be put into or removed from the body
cath lab/catheterization lab- another name for angiographic suite
diagnosis - the disease or condition that is causing symptoms
embolus (plural is emboli) - when something like a blood clot, air bubble or fatty deposit is released into the vessel and moves downstream with your blood flow. This may cause narrowing or blockage of the blood vessel

endovascular – through or inside blood vessels

fluoroscope – a kind of x-ray machine that is used to show the arteries to be treated

general anesthesia - medication given to make you sleep during the stenting procedure

intracranial - inside the head

intracranial arteries - the arteries inside the head that supply blood to the brain

ischemic stroke – a kind of stroke resulting from lack of blood flow to an area of the brain

local anesthesia - medication that numbs the body part being treated, so that you don't feel the discomfort of the stenting procedure.

neurovascular - blood vessels in, or leading to, the brain

sedation - medication given to make you very relaxed and sleepy

stenosis - a narrowing in your blood vessel

stent - a tiny wire mesh tube that is placed inside a blood vessel to keep it open

Transient Ischemic Attack (TIA) - temporary symptoms of stroke, such as problems seeing, speaking, or walking, that go away within 48 hours (see your doctor if you experience these symptoms)

vessel – the same as an artery

Potential Complications

Although stents (tiny wire mesh tubes that help to keep open clogged arteries) have been widely used in other vessels in the body, it is relatively new to put them in the arteries in the head. The possible benefit to you of choosing this treatment has not yet been proved to the FDA (Food and Drug Administration) by the manufacturer, Guidant Corporation.

There is always a chance of complications from endovascular procedures (procedures that are done through the blood vessels) including –

Allergic reactions, bleeding, heart attack, stroke or TIA (temporary symptoms of a stroke), or even death

Damage to your blood vessels

Emboli (air, blood clots, or even the stent breaking off moving downstream from where your doctor is working)

Restenosis (blocked blood flow in the stent)

Infection or bruising of your groin area (at the top of your leg) where the catheter (narrow tube) was inserted for the stent procedure.

If any of this happens to you, your doctor will treat you as needed.

Risks - Benefits

THIS STENT SHOULD NOT BE USED IF -

The narrowed area in the artery in your head is too small to allow the balloon catheter (tubing with a balloon at the end) and/or stent (tiny wire mesh tube) to fit into place.

You can't take blood thinners (anti-coagulants or anti-platelets), which are drugs that make your blood take longer to form a clot.

Note: Some doctors give combinations of anti-platelet and anti-coagulant drugs to decrease the risk that you will form a blood clot in your artery.

ATHEROSCLEROTIC DISEASE (ATHEROSCLEROSIS)

Atherosclerotic Disease

Its Causes

Atherosclerotic disease is caused by a build up of fatty substances like cholesterol. Where they collect in the blood vessel, the lining of the vessels thickens, the blood vessel narrows, and blood flow slows down. Atherosclerosis (the build up of fatty substances) can happen in any blood vessel in the body. Your symptoms have occurred because of atherosclerosis in the arteries in your brain.

Its Effects

Your brain is a very active organ. To work well, it needs a constant supply of oxygen and nutrient-rich blood. Four main arteries (two internal carotid arteries and two vertebral arteries) and a network of vessels supply the blood to your brain. If these arteries become partially blocked by fatty deposits, the brain may not receive enough oxygen and blood. In addition, blood clots can form at the narrowed part of the blood vessel or pieces of fatty build-up can be embolized (break off and release into the blood stream). At this point you may experience a stroke or TIA (transient ischemic attack, or temporary symptoms that seem like a stroke).

ISCHEMIC STROKE – TIAS

Reaching a Diagnosis

The Angiogram: This test is the main method used to diagnose (when your doctor decides the disease or condition that is causing your symptoms) the location and severity of atherosclerotic disease (a disease caused by a build up of fatty substances) in your blood vessels. A special dye is injected into the arteries in your head, and an x-ray is taken using a fluoroscope (a type of x-ray machine). The dye shows the arteries on a monitor (special television screen) so that your doctor can see the narrowed parts.

Remember - the sooner the diagnosis is made, the sooner treatment can begin.

Risk Factors for Atherosclerosis, Stroke, and TIA

Any of the following risk factors may increase your chances of developing atherosclerosis (a build up fatty substances inside the blood vessel)

Smoking
Diabetes
High blood pressure
Family history of atherosclerosis
Being overweight
Lack of exercise
High cholesterol diet

YOUR TREATMENT OPTIONS

Treatment Options

Once your doctor has made a diagnosis (the disease or condition that is causing your symptoms) he or she will recommend the most appropriate form of treatment. The most common treatment is medications. Other alternatives might include bypass surgery, angioplasty, or treatment with a stent (tiny wire mesh tube). There may be other options, and you should ask your doctor.

Medications

Your doctor may prescribe blood thinners known as anti-platelets or anti-coagulants. Common drugs used include aspirin, Plavix, Coumadin (also known as warfarin), or Aggrenox. These drugs lower the risk of blood clots forming at the narrowed part of the blood vessel, and can help relieve your symptoms.

Angioplasty

The purpose of angioplasty is to open blocked arteries to increase blood flow. The procedure will be done in an angiographic suite (a combinated x-ray and operating room) after giving you local anesthesia (medication given to numb the body part being treated) or general anesthesia (medication to make you sleep). A needle is put into a blood vessel in the groin (top of your leg) or arm. A catheter (small tube) is fed into your blood vessel. Contrast dye is injected through the catheter and your doctor uses a fluoroscope (a special x-ray machine) to see the arteries in your brain.

YOUR TREATMENT OPTIONS

While your doctor watches the picture of your arteries on the monitor (a special television screen), a wire and a balloon catheter (a tube with a small balloon on the end) are fed into the vessel. Your doctor will move the balloon into the narrowed part of the artery, and then inflate it to press the fatty deposits against the wall and stretch the artery. This increases the size of the artery and improves blood flow. The balloon is then deflated and removed. Over time the blockage may happen again. This is called "restenosis". If this happens, your symptoms might return and your doctor may recommend another treatment.

Bypass Surgery

With bypass, the surgeon bypasses or "goes around" the blocked artery to restore normal flow. A piece of blood vessel is taken from another part of the body and is sewn onto the blood vessel beyond the narrowed area. This makes a new path for the blood to flow past the narrowed area.

[Insert illustration of a bypassed vessel]

THE STENT PROCEDURE

Stenting

This treatment is similar to angioplasty (opening the blood vessel with a balloon; see page 9 for a description of angioplasty) except that a stent (tiny mesh wire tube) is used to help keep the artery open. Your doctor may recommend a stent in combination with asking you to take medications. A description of the NEUROLINK® Stent procedure follows below:

The NEUROLINK® Stent is a tiny wire mesh tube that is placed on a balloon catheter (a tube with a balloon at the end). The catheter is fed into the narrowed blood vessel.

The doctor moves the NEUROLINK® Stent on the balloon catheter into the blocked artery and inflates the balloon. This causes the stent to open up, pressing it against the vessel wall.

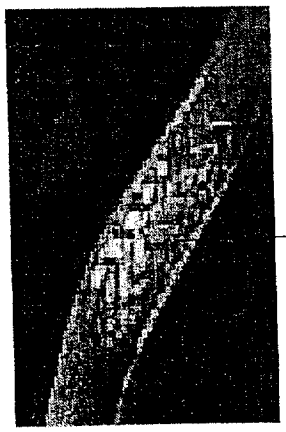
Then the balloon is deflated and removed from the vessel. The stent stays in place permanently.

THE STENT

The catheter is fed into the narrowed area of the artery caused by fatty build-up.

The balloon is inflated. This opens up the narrowed artery and expands the Stent.

The balloon and catheter are removed from inside the vessel. The Stent is left in place in the artery.



PREPARING FOR TREATMENT

In the days before your treatment, make sure you take all of the following PRECAUTIONS:

- Take all of your prescription medications
- Tell your doctor if you are taking any other medication
- Tell your doctor if, for any reason, you cannot take aspirin
- Make sure your doctor knows about any allergies you have
- Do not eat or drink after midnight on the night before your treatment
- Follow all instructions given to you by your doctor or your nurse

The procedure may be done under local or general anesthesia (medication that causes numbness or makes you fall asleep, so that you do not feel discomfort). If the doctor needs you to be perfectly still so that the x-ray picture is very clear, general anesthesia (medication that makes you fall asleep) might be used. If the doctor needs you to be awake so that you can take deep breaths and respond to instructions, local anesthesia (medication that will numb the body part being treated) may be used.

Once you are in the angiographic suite (the combinated x-ray and operating room where the procedure is performed) you will be moved onto an x-ray table and covered with a sterile sheet. Your groin (the area at the top of your leg) will be washed with an antibiotic solution, and a local anesthetic will be administered.

DURING THE PROCEDURE

Next, your doctor will put a needle into the artery (puncture site) in your groin (at the top of your leg) or arm to feed the stent (tiny wire mesh tube) on its balloon catheter (a tube with a balloon at the end) into the vessel. The procedure usually takes about 90 minutes. For the most part you will be comfortable -- but you may feel some pressure at the puncture site or headache or dizziness when the balloon is inflated. After a stent is put in an artery in the brain, some patients experience a headache that may take hours to go away.

Immediately after the procedure, you will be sleepy and may be confused from the sedation (the medication given to make you relaxed and sleepy) or general anesthesia (medication that makes you fall asleep), but this will clear as the medications wear off. You will be taken to a special room where you will be watched closely by the nurses and doctors: they will ask you questions, ask you to move your fingers and toes, and check your eyes with a flashlight. Your blood pressure and puncture site will also be closely watched.

[Insert an illustration showing vascular access of balloon catheter and stent]

MAKING A GOOD RECOVERY

During your stenting procedure (the procedure to place the stent, or tiny mesh tube, in your blood vessel), you will have been given a blood thinner (anti-coagulant). You may still have a sheath (thin tube placed inside the blood vessel) in your groin (top of your leg), which will be removed when the effects of the blood thinner wear off and your doctor decides that you are recovering from the stenting procedure. Pressure will be applied to puncture site (where the needle was placed in the vessel) until bleeding stops. Once you are awake, you should drink fluids to flush the dye out of your system. You will have to stay in bed for several hours, keeping your leg straight to allow your puncture site to start healing. Your doctor will allow you to gradually become more active. You will need to avoid lifting and straining for a couple of days. You may need to stay in the hospital for several days. After you are discharged, be sure to call your doctor or the hospital immediately if the symptoms you had before the procedure get worse, or if you have any new symptoms, such as -

- severe headache,
- dizziness
- slurred speech
- weakness on one side of your body (for example, your right arm, leg, or face becomes weaker than your left)
- fever
- problems at your puncture site such as swelling, pain, or bleeding.

GETTING ON WITH LIFE

To begin with, you will have to return for regular check-ups. After 6 months, you may be asked to have another angiogram (x-ray of your blood vessels using a contrast dye). Regular check-ups are the only way to check your progress, so please be sure to keep your appointments. Your doctor will also prescribe medication, and it is important to take your medication exactly as your doctor tells you. Be sure to take all of your medication until your doctor tells you to stop.

It may take weeks to months before you feel back to normal, and some effects from the stroke may be permanent. If you have had a stent (tiny wire mesh tube) placed in your brain, it will not limit your activities in any way. **It is very important to tell any doctor or dentist who treats you for any reason that you have a Stent implant in your brain, and keep your stent implant card with you at all times.** As the manufacturer of your stent, Guidant is required by the federal government to have your current address and telephone number on file. If your address or telephone number changes, please notify Guidant at 1 (800) 227-9902.

If anything you have read in this booklet has made you think of orther questions regarding the procedure, now is the time to discuss them with your doctor.

YOUR NOTES